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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/706,835      | 11/12/2003  | Kenneth G. Carson    | 1855.2036-001       | 6925             |

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/706,835 | <b>Applicant(s)</b><br>CARSON ET AL. |  |
|                              | <b>Examiner</b><br>Evelyn Huang      | <b>Art Unit</b><br>1625              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 18-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 18-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-11, 13, 18-63 are pending.

#### ***Claim Rejections - 35 USC § 112***

2. The rejection for Claims 5, 10, 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. The rejection is applicable to new claim 23.

Applicants maintain that the specification has satisfy the written description requirement and one of ordinary skill in the art would conclude that at the time the application was filed, applicants had possession of the claimed invention.

While certain diseases characterized by pathogenic leukocyte recruitment, pathogenic leukocyte activation or pathogenic leukocyte recruitment and activation have been described, the claims as recited in the instant claims 5, 10, 23 embrace and reach out to as yet unidentified diseases, the description of which is not found in the specification. The method of antagonizing a C-C chemokine receptor 1 embraces and reaches out to as yet unidentified diseases/conditions/activities, a description of which is not found in the specification.

#### ***Claim Rejections - 35 USC § 112***

3. The rejection for Claims 5, 10, 18 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The rejection is applicable to new claim 23.

Applicants contend that the examiner does not provide reasoning for the statement that claims directed to mediating a biological pathway are devoid identifiable utility and are therefore not useful. However, it is obvious and self-explanatory. The normal biological pathways in the body occur naturally and are not inventions. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility.

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Applicants maintain that the examiner's concerns regarding antagonism being inexorably linked to treatment of inflammatory disease are misplaced.

On the contrary, the inflammatory disease is mentioned only as an example of the disease treatment to illustrate that the instant claim directed to a mechanism of antagonizing the CCR1 receptor without the end result would therefore have no practical utility unless the antagonism of CCR1 receptor and the treatment of a disease are inexorably linked. However, the claims as recited embrace any degree of antagonism of the CCR1 receptor, which may or may not inexorably linked to the treatment of any disease.

While certain degree of experimentation is allowed, because the scope of the claims does commensurate with that of the objective enablement, especially in the absence of a full written description of the as yet unidentified diseases characterized by pathogenic leukocyte recruitment, pathogenic leukocyte activation or pathogenic leukocyte recruitment and activation, and of the as yet unidentified conditions/activities/disorders which the recited mechanism reaches out to, undue experimentation would be required for one of ordinary skill in the art to use the inventive compound as claimed,

### ***Claim Rejections - 35 USC § 103***

4. The rejection under 35 U.S.C. 103(a) as being obvious over Luly (US 2002/0169155) is maintained for reasons of record. The rejection is applicable to new claims 21-63.

Applicants argue that the combination of features that the examiner selected and relies on is not specifically disclosed by Luly. Furthermore, Luly does not exemplify the combination of 3,3-gem-dimethyl piperidine feature and the R<sup>40</sup> = -COOH.

If Luly were to exemplify the combination of 3,3-gem-dimethyl piperidine feature and the R<sup>40</sup> = -COOH, the rejection would be a 102 and not the instant 103.

In response to applicant's argument that there is no suggestion to combine the 3,3-gem-dimethyl piperidine feature and the R<sup>40</sup> = -COOH among the many possible combinations, the examiner recognizes that obviousness can only be established by combining or modifying the

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teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Luly generically discloses a chemokine receptor antagonist compound for treating inflammatory diseases. The instant compound is encompassed by Luly's generic compound. Luly's Example 438 (Fig. 15) has a 3-methyl on the piperidinyl whereas the instant has a 3,3 dimethyl on the piperidinyl. The addition of a methyl is an obvious modification to one of ordinary skill in the art in view of its close structural similarity. Furthermore, Luly, expressly teaches that 3-methyl and 3,3-dimethyl are optional choices (page 7, [0094]-[0096]). Moreover, an example of 3,3-dimethyl-piperidinyl is shown in Example 443 (Fig. 18)). At the time of the invention, one of ordinary skill in the art would be motivated to replace the 3-methyl with the exemplified, alternative 3,3-dimethyl on the piperidinyl to arrive at the instant invention with the reasonable expectation of obtaining an additional compound for treating inflammatory diseases, since Luly had clearly teaches any species within the disclosed genus, especially the exemplified compounds, would be effective CCR1 antagonist useful for treating inflammatory diseases.

The prior art compound includes the enantiomers, and the enantiomer compound of claim 6 is therefore obvious over the racemic example compound, as Luly expressly pointed out (column 9, [0129]). To one of ordinary skill in the art, the N-oxide compound of claim 19 is an obvious modification of the prior art example N-compound.

Indeed, Luly discloses a broad genus of compounds supported by over hundreds of examples with different combinations of substituents. The sheer number of examples, however, does not negate the teaching and suggestion of Luly towards combining 3,3-gem-dimethyl piperidine feature and the  $R^{40} = -COOH$  to arrive at the instant, especially when these substituents are generically disclosed and both are specifically exemplified.

### ***Conclusion***

5. No claims are allowed.

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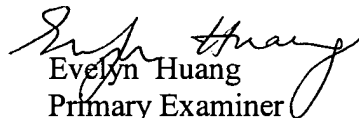
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
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